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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/685,139

10/14/2003

Steve Mitchell

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65901 7590 09/04/2008
COATS & BENNETT/MEDTRONIC
1400 CRESCENT GREEN
SUITE 300
CARY, NC 27518

EXAMINER

HOFFMAN, MARY C

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

09/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/685,139	Applicant(s) MITCHELL, STEVE	
	Examiner MARY HOFFMAN	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7,9-16,20-24,26-56,58-64 and 66-85 is/are pending in the application.
- 4a) Of the above claim(s) 70-76 and 78-81 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 26-56,58-64,66-69,77 and 83-85 is/are allowed.
- 6) ☒ Claim(s) 7,9-16,20-24 and 82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/23/2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what the claim limitation “defining a minimum distance between lamina...L5 vertebra” is referring to. Since the examiner cannot find similar terminology in the specification to help clarify the meaning of this claim limitation, this recitation is considered indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 9, 12-16 and 20-24 rejected under 35 U.S.C. 102(e) as being anticipated by Zucherman et al. (U.S. Patent App. No 2002/0029039).

Zuckerman discloses an implant comprising a body; at least one hook extending from the body and adapted to allow the body to engage a SI vertebra; a brace extending from the body and including an elongated shape with a major axis and a minor axis, wherein the brace has a distal end on the major axis adapted for contacting an inferior surface of a spinous process of the a L5 vertebra during extension of the spine; and a device that can secure the brace to the body (see e.g. FIGS. 131, 137, 141). The implant is comprised of titanium. The device can secure the brace to the body in a plurality of positions. The distal end is bulbous. The distal end is round. The distal end provides a surface which is at an angle to a beam of the brace, which surface is adapted to engage the L5 vertebra. The distal end includes a convex surface that is adapted to engage a spinous process of the L5 vertebra to spread the load between the distal end and the spinous process. The brace includes an elongated aperture and the

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device extends through the aperture and can be secured to the aperture in a plurality of positions in order to position the brace relative to the body in a plurality of positions. The body includes a first portion and a second portion with a beam platform located between the first and second portions and the beam platform spaced from the first and second portions in order to space the brace from the first and second portions. The hook extends from the first portion and another hook extends from the second portion. The device extends from the platform.

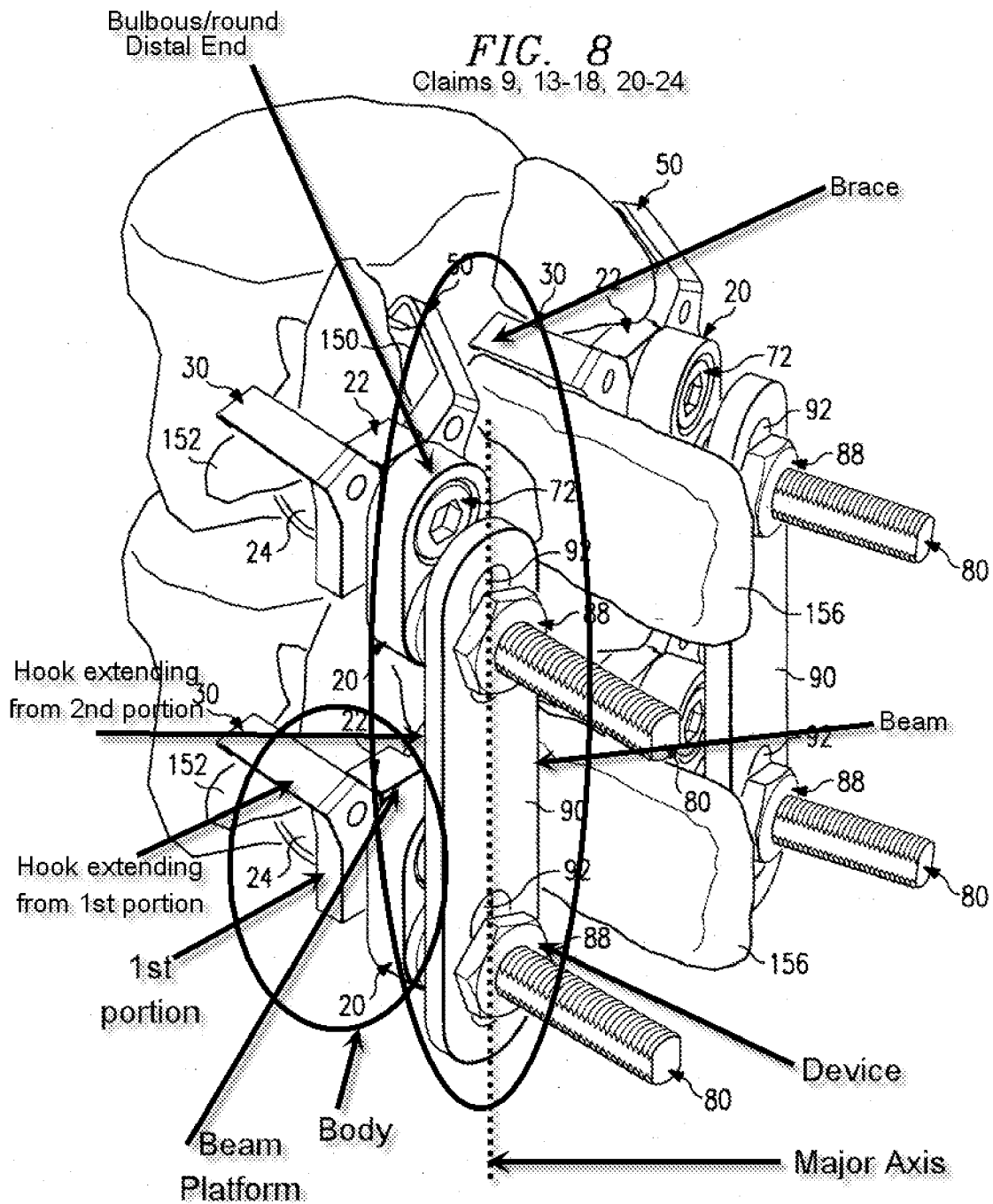
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 13-16, 20-24 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (U.S. Patent No. 5,415,659).

Lee et al. discloses the claimed invention. The rejection is illustrated in the below marked-up figure. The claims features are labeled in the below marked-up figures.

CLAIMS 9, 13-18 and 20-24

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (U.S. Patent No. 5,415,659).

Lee et al. disclose the claimed invention except for the implant being made from a material such as polyetheretherketone, polyaryletheretherketone, and polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone, or titanium.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct at least a part of the device of Lee et al. from a material such as polyetheretherketone, polyaryletheretherketone, polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone, or titanium, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zucherman et al. (U.S. Patent App. No 2002/0029039).

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Zucherman et al. disclose the claimed invention except for the implant being made from a material such as polyetheretherketone, polyaryletheretherketone, and polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone

It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct at least a part of the device of Zucherman et al. from a material such as polyetheretherketone, polyaryletheretherketone, polyetherketoneketone, polyetherketoneetherketoneketone, polyetheretherketoneketone, polyketone, polyetherketone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Allowable Subject Matter

Claims 26-56, 58-64, 66-69, 77 and 83-85 are allowed.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed 06/23/2008 have been fully considered but they are not persuasive with regard to independent claim 9 and dependent claims thereof.

With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Lee, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference “teach” what the subject patent teaches, but rather it is only necessary that the claims under attack “read on” something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Claim 9 does not require that the brace be adapted for contacting the inferior surface “while implanted”, therefore, the Lee device is capable of performing the claimed function of being adapted to contact the inferior surface.

The rejections are deemed proper.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733